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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,270	01/26/2002	George E. Fox	010AUS	3019
26830 7590 06/09/2009 RICHARD COALE WILLSON JR 3205 HARVEST MOON DR STE 200 PALM HARBOR, FL 34683-2127				
EXAMINER				
SIMS, JASON M				
ART UNIT		PAPER NUMBER		
1631				
MAIL DATE		DELIVERY MODE		
06/09/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/057,270

**Applicant(s)**

FOX ET AL.

**Examiner**

JASON M. SIMS

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-10, 19, 21, 23, 24, 28, 29 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-10, 19, 21, 23, 24, 28-29, and 39-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's arguments, filed 3/11/2009, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 3/11/2009, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant has newly added claims 39-46 in the response filed 3/11/2009, which have been acknowledged and entered.

Applicant's cancellation of claims 25-27 in the response filed 3/11/2009 is acknowledged.

Claims 4-10, 19, 21, 23, 24, 28-29, and 39-46 are the current claims hereby under examination.

***The following rejections are being newly applied, which have been necessitated by amendment:***

#### ***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-10, 19, 21, 23, 24, 28-29, and 39-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 4 and 40 and all claims dependent therefrom comprise step C, wherein the amendment "computationally fragmenting each target nucleic acid sequence so as to create a subsequence database of nucleic acid subsequences of length N" has been deemed as new matter. Applicant has pointed to page 18, lines 33-37 for support for said computationally fragmenting, wherein support has not been found. Said page 18, lines 33-37 refers to the program probes\_hash\_table\_generator, which appears to operate on specific type of sequences, i.e. 16s rRNA sequences, which it then excises oligonucleotides of specified length, wherein the amended claim step is directed to computationally fragmenting any type of target nucleic acid sequence, which may or may not include 16s rRNA sequences. Therefore, the amended claim step does not appear to have support where pointed to by applicant.

***Claim Rejections - 35 USC § 112-Second Paragraph***

***Response to Arguments***

Applicant's arguments, filed 3/11/2009, with respect to the rejections of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendments to the claims. Therefore the rejections have been withdrawn.

***The following rejections are being newly applied, which have been necessitated by amendment:***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-10, 19, 21, 23, 24, 28-29, 39-44, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 40 (and all claims dependent therefrom), step D, recites the wording "creating a signature database," wherein what comprises the "signature database" has been deemed as vague and indefinite. Step D, describes creating a database, but only discloses a method step for performing a calculation, i.e. "tabulating the extent to which the presence of each particular nucleic acid subsequence of length N in the subsequence database is characteristic of each node in the bifurcating phylogenetic tree of genetic relationship by examining the occurrence frequency of each subsequence in the target nucleic acid of the organisms and viruses encompassed by or not encompassed by each node in the tree." Therefore, it is unclear as to what data comprises the "signature database" with regards to the calculated characteristics of each nucleic acid subsequence. Clarification via clearer claim wording is required.

Claim 4 (and all claims dependent therefrom), step E recites the limitation "the signature database of characteristic signature sequences" in lines 1-2 of step E. The wording appears to refer back to the signature database created in step D, wherein the database does not appear to be comprised of "signature sequences." The signature

database created in step D only appears to be comprised of tabulated characteristics, which are based on an occurrence frequency. There is no recitation in step D of a signature database comprised of "signature sequences." Therefore, there is insufficient antecedent basis for this limitation in the claim.

Claim 40 (and all claims dependent therefrom), step E, has been deemed as vague and indefinite. It is unclear as to how signature probes are derived from a signature database, wherein it is unclear as to what data comprises the signature database. Therefore, it is unclear as to how to further derive signature probes from a database wherein it is unclear as to what data comprises the signature database. Clarification via clearer claim wording is required.

***The following rejections are being newly applied, which have been necessitated by amendment:***

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 40 and 45 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter.

Claims 40 and 45 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

In the instant case, the claims are drawn to a method of determining the genetic affinity of organisms or viruses in a test sample. The recited process involves the abstract and computational steps of creating databases, computationally fragmenting target nucleic acid sequences, and deriving a plurality of signature probes from the signature database. As such, the instant claims do not recite any to a particular machine or apparatus, nor do the instant claims involve a transformation of a particular article. The final step of deriving a plurality of signature probes has been interpreted as reading on computationally deriving a plurality of signature probes, wherein the step is not necessarily carried out in the physical realm. Therefore, the instant claims are drawn only to an abstract process that only manipulates data and, therefore, are not directed to statutory subject matter.

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir. 1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

***Claim Rejections - 35 USC § 102***

***Response to Arguments***

Applicant's arguments, filed 3/11/2009, with respect to the rejection of claims have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejection has been withdrawn.

***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.



If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin/  
Primary Examiner, Art Unit 1631